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Applicants: Morris Reichlin and Eugene Koren

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Assistant Commissioner for Patents
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INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 08/800,682, filed February 14, 1997, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,602,003	07-22-1986	Malinow	514/26
4,944,944	07-31-1990	Tang, et al.	424/94.6
4,976,968	12-11-1990	Steiner	424/491
5,017,565	05-21-1991	Lange III, et al.	514/54
5,063,210	11-05-1991	Lange, III, et al.	514/54
5,173,408	12-22-1992	Lange, III, et al.	435/69.1
5,200,183	04-06-1993	Tang, et al.	424/94.6
5,376,640	12-27-1994	Miyazaki, et al.	514/12
5,519,001	05-21-1990	Kushwaha, et al.	514/12
RE 33,885	04-14-1992	Mattson	514/53

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
0 333 523	09-20-1989	The UAB Research Foundation	EP
WO 89/08465	09-21-1989	Teruno Kabushiki Kaisha	PCT
WO 91/06286	05-16-1991	Enzytech, Inc.	PCT
WO 91/06287	05-16-1991	Enzytech, In,c	PCT
WO 91/15234	10-17-1991	Oklahoma Medical Research Foundation	PCT
WO 94/20610	09-15-1994	Aktiebolaget Astra	PCT

Publications

AARDEN, et al., "Immunology Of DNA. III. Crithidia Luciliae, A Simple Substrate For The Determination Of Anti-dsDNA With The Immunofluorescence Technique," *Ann. NY Acad. Sci.* 254:505-515 (1975).

ALTSCHUL, et al., "Basic Local Alignment Search Tool," *J. Mol. Biol.* 215:403-410 (1990).

ANDRE-SCHWARTZ, et al., "Binding Of Cytoskeletal Proteins By Monoclonal Anti-DNA Lupus Autoantibodies," *Clin. Immunol. Immunopathol.* 31:261 (1984).

BARADA, et al., "Antibodies To Sm In Patients With Systemic Lupus Erythematosus," *Arthritis Rheum.* 24:1236-1244 (1981).

BEAULIEU, et al., "IgG Antibodies To Double-Stranded DNA In Systemic Lupus Erythematosus Sera," *Arthritis Rheum.* 22:565-570 (1979).

BLOOM, et al., "Overlap Of The Anti-Sm And Anti-DNA Responses Of MRL/Mp-lpr/lpr Mice," *J. Immunol.* 150:1579 (1993).

BOREL, et al., "Prevention Of Murine Lupus Nephritis By Carrier-Dependent Induction Of Immunologic Tolerance To Denatured DNA," *Science* 182:76-77 (1973).

BOREL, et al., "Treatment Of Lupus Nephritis In Adult (NZB+ NZW)F Mice By Cortisone-Facilitated Tolerance To Nucleic Acid Antigens," *J. Clin. Invest.* 61:276-286 (1978).

BOREL & BOREL, "Oligonucleotide Linked To Human Gammaglobulin Specifically Diminishes Anti-DNA Antibody Formation In Cultured Lymphoid Cells From Patients With Systemic Lupus Erythematosus," *J. Clin. Invest.* 82:1901-1907 (1988).

CLACKSON, et al., "Making Antibody Fragments Using Phage Display Libraries," *Nature* 352:624-688 (1991).

CLARK, et al., "Characterization Of A Soluble Cytoplasmic Antigen Reactive With Sera From Patients With Systemic Erythmatosus," *J. Immunol.* 102(1):117-122 (1969).

DALE, et al., "A Rapid Single-Stranded Cloning Strategy For Producing A Sequential Series Of Overlapping Clones For Use In DNA Sequencing: Application To Sequencing The Corn Mitochondrial 18S rDNA," *Plasmid* 13:31-40 (1985).

DAUGHERTY, et al., "Polymerase Chain Reaction Facilitates The Cloning, CDR-Grafting, And Rapid Expression Of A Murine Monoclonal Antibody Directed Against The CD18 Component Of Leukocyte Integrins," *Nucl. Acids Res.* 19:2471-2476 (1991).

DEVEREUX, et al., "A Comprehensive Set Of Sequence Analysis Programs For The VAX," *Nucleic Acids Res.* 12:387-395 (1984).

DIVALERIO, et al., "Anti-DNA Antibodies Can React Specifically With DNA In The Context Of Glomeruli," *Clin. Res.* 42:139A (1994).

EKLUND, et al., "Cloning Of A cDNA Encoding A Human DNA-Binding Protein Similar To Ribosomal Protein S1," *Gene* 155:231-235 (1995).

FRANZETTI, et al., "Characterization And RNA-Binding Properties Of A Chloroplast S1-Like Ribosomal Protein," *J. Biol. Chem.* 267:19075-19081 (1992).

FRIGUET, et al., "Measurement Of The True Affinity Constant In Solution Of Antigen-Antibody Complexes By Enzyme-Linked Immunosorbent Assay," *J. Immunol. Methods* 77:305 (1985).

GISH & STATES, "Identification Of Protein Coding Regions By Database Similarity Search," *Nature Genetics* 3:266-271 (1993).

GONZALEZ & ROTHFIELD, "Immunoglobulin Class And Pattern Of Nuclear Fluorescence In Systemic Lupus Erythematosus," *N. Engl. J. Med.* 274:1333-1338 (1966).

HAMILTON, et al., "Two Ro (SS-A) Autoantibody Responses In Systemic Lupus Erythematosus," *Arthritis Rheum.* 31:496-505 (1988).

HANDWERGER, et al., "Palmerston North Mice Produce Antibodies To U1RNP And SM Particles," *Clin. Res.* 42:315A (1994).

HAHN & TSAO, "Antibodies To DNA: In Dubois, Systemic Lupus Erythematosus, Wallace & Hahn, Eds. Lea & Febiger, Philadelphia, PA, 195-201 (1993).

HAHN & EBLING, "Suppression of murine lupus nephritis by administration of an anti-idiotypic antibody to anti-DNA," *J Immunol* 132(1):187-90 (1984).

HARLEY, et al., "A Model For Disease Heterogeneity In Systemic Lupus Erythematosus: Relationship Between Histo-Compatibility Antigens, Autoantibodies, And Lymphopenia, Or Renal Disease," *Arthritis Rheum.* 32(7):826-836 (1989).

ITOH, et al., "Heterogeneity Of The Ro/SSA Antigen And Autoanti-Ro/SSA Response: Evidence Of The Four Antigenically Distinct Forms," *Clin. Exp. Immunol.* 81:45-51 (1990).

JACO, et al., "Human Systemic Lupus Erythematosus Sera Contain Antibodies Against Cell Surface Protein(s) That Share(s) Epitope(s) With DNA," *Proc. Natl. Acad. Sci. USA* 83:6970 (1986).

JAENISCH, "Transgenic Animals" *Science* 240:1468-1474 (1988).

KABAT, et al., "Sequences Of Proteins Of Immunological Interest, 4th Ed. (U.S. Dept. Health and Human Services, Bethesda, MD (1987).

KASUKAWA & SHARP, Ed. (Excerpta Medica, Elsevier Science Pub., Amsterdam, 85-96 Mixed Connective Tissue Disease And Anti-Nuclear Antibodies (1987).

KOFFLER, et al., "Antibodies To Polynucleotides In Human Sera: Antigenic Specificity And Relation To Disease," *J. Exp. Med.* 134:294-312 (1971).

KOREN, et al., "Murine and Human Antibodies to Native DNA that Cross-React with the A and D SnRNP Polypeptides Cause Direct Injury of Cultured Kidney Cells," *J. Immunol.* 154(9):4857-4864 (1995).

LEONING, "The Frantionation of High-Molecular-Weight Ribonucleic Acid aby polyacrylamide-Gel Electrophoresis," *Biochem. J.* 102:251 (1967).

MADDISON, et al., "Patterns Of Clinical Disease Associated With Antibodies To Nuclear Ribonucleoprotein," *J. Rheumatol.* 5:407-411 (1978).

MADDISON & REICHLIN, "Deposition Of Antibodies To A Soluble Cytoplasmic Antigen In The Kidneys Of Patients With Systemic Lupus Erthematosus," *Arthritis Rheum.* 22:858-863 (1979).

MATTER, et al., "Molecular Characterization of Ribonucleoprotein Antigens Bound by Antinuclear Antibodies," *Arthritis Rheum* 25:1278 (1982).

MATTIOLI, et al., "Heterogeneity Of RNA Protein Antigens Reactive With Sera Of Patients With Systemic Lupus Erythematosus," *Arthritis Rheum.* 17:421-429 (1974).

MATTIOLI, et al., "Characterization Of A Soluble Nuclear Ribonucleoprotein Antigen Reactive With Sle Sera," *J. Immunol.* 107(5):1281-1290 (1971).

MINITER, et al., "Reassessment Of The Clinical Significance Of Native DNA Antibodies In Systemic Lupus Erythematosus," *Arthritis Rheum.* 22(9):959-968 (1979).

PENNEBAKER, "Immunoglobulin Classes of DNA Binding Activity in Serum and Skin in Systemic Lupus Erythematosus," *Journal of Clinical Investigation* 60:1331-1338 (1977).

PISETSKY, et al., "Specificity And Idiotypic Analysis Of A Monoclonal Anti-Sm Antibody With Anti-DNA Activity," *J. Immunol.*, 135:4080 (1985).

POORMAN, et al., "Isolation and Characterization of Native Human Renin Derived From Chinese Hamster Ovary Cells," *Proteins: Structure, Function and Genetics* 1(2):139-145 (1986).

PROVOST, et al., "Lupus Band Test in Untreated SLE Patients: Correlation of Immunoglobulin Deposition in the Skin of the Extensor Forearm with Clinical Renal Disease and Serological Abnormalities," *Journal of Investigative Dermatology* 74(6):407-412 (1980).

RADIC, et al., "Residues That Mediate DNA Binding Of Autoimmune Antibodies," *J. Immunol.* 150:4966 (1993).

RAZ, et al., "Anti-DNA Antibodies Bind Director To Renal Antigens And Induce Kidney Dysfunction In The Isolated Perfused Rat Kidney," *J. Immunol.* 142:3076 (1989).

RAZ, et al., "Cross-reactions of anti-DNA autoantibodies with cell surface proteins," *Eur. J. Immunol.* 23:383-390 (1993).

REICHLIN & MATTIOLI, "Correlation Of A Precipitin Reaction To An Rnprotein Antigen And A Low Prevalence Of Nephritis In Patients With Systemic Lupus Erythematosus," *N. Engl. J. Med.* 286:908-911 (1972).

REICHLIN, et al., "Lupus Autoantibodies To Native DNA Cross-React With THE A And D SnRNP Polypeptides," *J. Clin. Invest.* 93:443-449 (1994).

REICHLIN, et al., "Characterization of Anti-dsDNA Antibodies: Cross Reaction with SnRNP Polypeptides and Cell-Binding Abilities," *The Immunologist* 3/3 84-88 (1995).

SASAKI, et. al., "Selective elimination of anti-DNA antibody-producing cells by antiidiotypic antibody conjugated with neocarzinostatin," *J Clin Invest* 77(4):1382-6 (1986).

SANGER, et al., "DNA Sequencing With Chain Terminating Inhibitors," *Proc. Natl. Acad. Sci. USA* 74:5463-5467 (1977).

SCHNIER & FAIST, "Comparison Studies On The Structural Gene For The Ribosomal Protein S1 In Ten Bacterial Species," *Mol. Gen. Genet.* 200:476-481 (1985).

SCHNIER, et al., "Cloning And Characterization Of A Gene From Rhizobium Melilotii 2011 Coding For Ribosomal Protein S1," *Nucleic Acids Res.* 16:3075-3089 (1998).

SCHUR & SANDSON, "Immunological Factors And Clinical Activity In Systemic Lupus Erythematosus," *N. Engl. J. Med.* 278:533-538 (1982).

SHARP, et al., "Mixed Connective Tissue Disease-An Apparently Distinct Rheumatic Disease Syndrome Associated With A Specific Antibody To An Extractable Nuclear Antigen (ENA)," *Am. J. Med.* 52:148-159 (1972).

SMITH & JOHNSON, "Single-step Purification Of Polypeptides Expressed In Escherichia Coli As Fusions With Glutathione S-transferase," *Gene (Amst.)*, 67:31 (1988).

SUBRAMANIAN, "Structure And Functions Of Ribosomal Protein S1," *Prog. Nucleic Acids Res. Mol. Biol.* 28:101-142 (1983).

TALAL, et al., "Immunologic Regulation of Spontaneous Antibodies to DNA and RNA; I. Significant of IgM and IgG Antibodies in SLE Patients and Asymptomatic Relatives," *Clin. exp. Immunol.* 25:377-382 (1976).

TAN & KUNKEL, "Characteristics Of A Soluble Nuclear Antigen Precipitating With Sera Of Patients With Systemic Lupus Erythematosus," *J. Immunol.* 99(3):464-471 (1996).

TAN, et al., "Deoxyribonucleic Acid (DNA) And Antibodies To DNA In The Serum Of Patients With Systemic Lupus Erythematosus," *J. Clin Invest.* 45:1732-1740 (1966).

TARGOFF, et al., "Anti-KJ: A New Antibody Associated with the Syndrome of Polymyositis and Interstitial Lung Disease," *J. Clin. Invest.* 84:162.

TSAO, et al., "Structural Characteristics Of The Variable Regions Of Immunoglobulin Genes Encoding A Pathogenic Autoantibody In Murine Lupus," *J. Clin. Invest.* 85:530-540 (1990).

TSUZAKA, et al., "Lupus Autoantibodies to Double-Stranded DNA Cross-React with Ribosomal Protein S1," *Journal of Immunology* 156:1668-1675 (1996).

VLAHAKOS, et al., "Murine Monoclonal Anti-DNA Antibodies Penetrate Cells, Bind To Nuclei, And Induce Glomerular Proliferation And Proteinuria In Vivo^{1,2}," *J. Am. Soc. Nephrol.* 2:1345-1354 (1992).

WASICEK & REICHLIN, "Clinical And Serological Differences Between Systemic Lupus Erythematosus Patients With Antibodies To Ro Versus Patients With Antibodies To Ro And La," *J. Clin. Invest.* 69:835-843 (1982).

WINFIELD, et al., "Specific Concentration Of Polynucleotide Immune Complexes In The Cryoprecipitates Of Patients With Systemic Lupus Erythematosus," *J. Clin. Invest.* 56:563-570 (1975).

WINKLER, et al., "IgG Human Monoclonal Anti-DNA Autoantibodies From Patients With Systemic Lupus Erythematosus," *Clin. Exp. Immunol.* 85:379-385 (1991).

YANASE, et al., "A Subgroup Of Murine Monoclonal Anti-Deoxyribonucleic Acid Antibodies Of Murine Monoclonal Anti-Deoxyribonucleic Acid Antibodies Traverse The Cytoplasm And Enter The Nucleus In A Time-And Temperature-Dependent Manner," *Lab. Invest.* 71:52-60 (1994).

YOUNG & DAVIS, "Efficient Isolation Of Genes By Using Antibody Probes", *Proc. Natl. Acad. Sci. USA* 80:1194-1198 (1983).

ZACK, et al., "DNA Mimics A Self-Protein That May Be A Target For Some Anti-DNA Antibodies In Systemic Lupus Erythematosus," *J. Immunol.* 154:1987 (1995).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

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ARNALL GOLDEN & GREGORY, LLP
2800 One Atlantic Center
1201 W. Peachtree Street
Atlanta, Georgia 30309-3450
(404) 873-8794
(404) 873-8795 (fax)